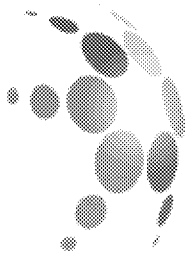

FluoroCouncil
Global Industry Council
for FluoroTechnology

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Dr. Doa:

The FluoroCouncil is a global membership organization representing the world's leading manufacturers of fluoropolymers, fluorotelomers, and other fluorinated surfactants and surface property modification agents.[1] The FluoroCouncil has a fundamental commitment to product stewardship and, as part of its mission, addresses science and public policy issues related to FluoroTechnology.

As you know, the members of FluoroCouncil have been EPA's partners in the implementation of the PFOA Stewardship Program, one of the most effective government-industry collaborations in the Agency's history to phase-out a family of chemicals that raised public concerns. In conjunction with this phase-out, FluoroCouncil members also developed a new generation of short-chain fluorinated substances that offered comparable technical and economic performance, while presenting a health and environmental profile that was superior to PFOA and its precursors. Through the TSCA New Chemicals Program, EPA has assessed these substances and authorized their entry into commerce.

Based on the recent experience of one of our members in the TSCA New Chemicals Program, we understand that EPA is considering a modification of the risk assessment uncertainty factor

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[1] The FluoroCouncil's members are Archroma Management LLC, Arkema France, Asahi Glass Co., Ltd., Daikin Industries, Ltd., The Chemours Company, and Solvay Specialty Polymers.

[2] Nilsson H, Kärrman A, Westberg H, Rotander A, Van Bavel B, and Lindström, G. A Time Trend Study of Significantly Elevated Perfluorocarboxylate Levels in Humans after Using Fluroinated Ski Wax. *Environmental Science and Technology.* 2010, 44, 2150-2155.

[3] Additional references include:
Nilsson, H, Kärrman, A., Rotander A, van Bavel B, Lindström, G, Westberg H. Biotransformation of fluorotelomer compound to perfluorocarboxylates in Humans. *Environment International* 2013, 51, 8-12.
Russell MH, Nilsson H, Buck RC. Elimination kinetics of perfluorohexanoic acid in humans and comparison with mouse, rat and monkey. *Chemosphere* 2013, 93, 2419-2425.

being used to evaluate the elimination kinetics of Perfluorohexanoic Acid ("PFHxA"), the common degradant of many C6 fluorotelomer-based substances that are being developed to replace PFOA-related C8 chemistry. Specifically, we understand that EPA is considering the reported PFHxA blood levels from ski wax technicians to adjust elimination half-life data from animal studies to account for possible higher retention of PFHxA in the human body.[2]

The ski wax technician data, which was collected primarily between 2007 and 2010, has been the subject of several published articles.[2,3] FluoroCouncil believes that it is essential for EPA to consider the original blood concentration data set that was generated on the ski wax technicians. Accordingly, we are providing the individual ski wax technician data tables from the Nilsson, et al. 2010 article as an attachment to this letter.[2,]

For purposes of calculating a risk assessment uncertainty factor and determining whether a policy adjustment of this nature is warranted, FluoroCouncil does not believe use of the ski wax technician data is scientifically appropriate to change EPA risk assessment policy on PFHxA, in light of the following considerations:

1. The authors of the original paper stated that the purpose of the ski wax technician study was "to determine if persons frequently exposed to fluorinated ski waxes have elevated blood levels of PFCs compared to the general population."[2] The researchers who collected the data further noted that the data could be used "to assess temporal trends of the levels over one year covering the exposed period of cross-country World Cup season 2007/2008 as well as the unexposed months before and after the ski season."[2]

2. Importantly, to assess and quantify human elimination kinetics in a scientifically sound manner, daily, and perhaps hourly data points would be required to be able to calculate a PFHxA blood elimination half-life for any individual. This is particularly significant for PFHxA, since all the available animal blood elimination data shows rapid elimination in less than 12-24 hours in males and females across three species (rat, mouse, and monkey). The ski wax worker study authors recognized this when interpreting their study data.

   The study authors state that the study data support a "fast elimination" of the compound in humans, consistent with results in animal studies. They note, however, that "it is not possible to calculate an exact terminal half-life" from the data in the study "since the sampling interval is 4 weeks and the PFHxA levels decrease <LOD for most technicians in that period of time."[2] Thus, use of the ski wax data to calculate or estimate a specific half-life for humans, or develop a ratio between putative human half-life and an animal half-life measured in controlled studies, is scientifically inappropriate and takes the ski wax technician data beyond its original intent and purpose.

3. Specifically, each technician was sampled roughly once a month although the precise sampling intervals are not clarified in the study. No technician was sampled consistently every month during the 2007/2008 ski season, and before and after that season, for a

[4] Supplemental data from Nilsson H, Kärrman A, Westberg H, Rotander A, Van Bavel B, and Lindström, G. A Time Trend Study of Significantly Elevated Perfluorocarboxylate Levels in Humans after Using Fluroinated Ski Wax. *Environmental Science and Technology*. 2010, 44, 2150-2155.

consecutive 12 month period. Only six of the eleven technicians in the study were sampled for at least three months in a row.[4]

In order to adequately assess blood elimination kinetics of PFHxA in humans, control subjects with no exposure to PFHxA and subjects exposed to PFHxA would be sampled at the same time and over a consecutive period of time. Ideally, the exposure group would have had no previous exposure or would have a well-defined time period of no exposure to PFHxA prior to the beginning of the study. Additionally, the study population should be well characterized in regards to the frequency of exposure, length of exposure and route of exposure. Also, samples would be taken at relevant time intervals (e.g., days, hours) to clearly be able to characterize blood elimination kinetics.

4. An examination of the underlying study data (see the plots tables from the original paper that are attached) raises serious doubt about any hypothesis suggesting that PFHxA has a significantly longer half-life in humans than in primates. The data show a decline in PFHxA levels from month to month during the ski season. Nilsson reports that the relevant ski season for the study was December 2007 to March 2008. Yet the data report several examples where there was a sharp drop in PFHxA levels between December 2007 and January 2008 (Technician 1: 12.20 ng/mL to 2.52 ng/mL; Technician 2: 4.84ng/mL to <0.07 ng/mL; Technician 3: 5.40 ng/mL to 0.33 ng/mL.) Another aspect of the data is that several of the technicians (Technicians 4, 6 and 7) showed consistently low PFHxA blood concentrations throughout the ski season, when exposure should be at its highest. For four of the technicians (Technicians 2, 3, 4 and 6), there were PFHxA data for the end of the ski season (March) and the beginning of the off-season (April). In all four cases, the data show a sharp decline in the PFHxA levels.[4]

   In highlighting these data, FluoroCouncil is not asserting that these data should be used to establish any particular half-life in humans. The data are just too sparse to support any specific calculation. Our key point is that these data do not support, and should not be cited to support, an assumption that the PFHxA half-life in humans is significantly longer than the measured half-life of the substance in primates.

5. Perhaps the core scientific data absent from the ski wax technician data is data collected during a depuration period following their highest exposure to PFHxA, within the 24 hour period immediately following work exposure. According to the original researchers who collected the data, the ski wax technicians applied fluorinated ski wax "for approximately 30 hours a week" during the "exposed skiing season from December to March."[3] Thus, the technicians involved in this study were subject to repeated daily doses of many fluorinated substances in the commercial ski wax, including PFHxA, for a sustained period of time. No information can be gleaned from the study data that informs what the practical depuration period of PFHxA was during the ski season, as the appropriate samples to address this question were not taken.

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[5] Chengelis CP, Kirkpatrick JB, Myers NR, Shinohara M, Stretson PL, Sved DW. Comparison of the toxicokinetic behavior of perfluorohexanoic acid (PFHxA) and nonafluorobutane-1-sulfonic acid (PFBS in cynomolgus monkeys and rats. Reproductive Toxicology. 2009, 27, 400-406.

In the period immediately following the end of the ski season (April 2008), there was no systematic collection of blood samples during the hours and days that followed the end of the exposure period for any individual. As noted above, the data include single March-to-April 2008 comparison measurements for only four individuals. These data showed a sharp drop in PFHxA levels, which is consistent with the "fast elimination" conclusion by the authors of Nilsson (2010). At the same time, this level of sampling was clearly inadequate to provide a basis for a half-life calculation or estimate that would be comparable to the available data on PFHxA in blood samples from controlled studies of rodents and primates.

As we understand EPA's current approach to risk assessment of PFHxA in the New Chemicals Program, the Agency has already adjusted its uncertainty factor for toxicokinetics to account for differences in blood elimination half-lives between rodents and primates. Since the specifics of those calculations have not been made available to all FluoroCouncil members, we are not in a position to endorse the uncertainty factor that EPA is currently using for that purpose. We note, however, that there are valid controlled studies of PFHxA half-life in primates and rodents that do provide a basis for such an adjustment in the uncertainty factor.[5]

In contrast, there are not adequate human blood elimination data available at this time to support a chemical-specific adjustment factor to account for possible toxicokinetic differences in PFHxA between animals and humans. Certainly for the reasons outlined above, the ski wax technician data do not provide a scientifically valid basis for such a change in policy.

FluoroCouncil would be very interested to meet with EPA to discuss this specific issue in more detail and to offer some broader thoughts about how the Agency might address the toxicokinetics of short chain substances, including PFHxA.

Thank you for your attention to this matter. If you have any questions or would like any additional information, please contact me at (202) 249-6700 or robert_simon@fluorocouncil.com.

Sincerely,

Robert J. Simon
FluoroCouncil

cc: Tala Henry, Ph.D, Director, Risk Assessment Division

Enclosures
- Nilsson et al. 2010 paper and supplemental data